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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,302	12/10/1999	JOHN FIKES	18623-014400	8701

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EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/458,302

Applicant(s)

FIKES ET AL.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-167 is/are pending in the application.
- 4a) Of the above claim(s) 42, 44-52, 54-65, 67-71, 74, 76 and 79-167 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 41, 43, 53, 66, 72, 73, 75, 77, 78 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Art Unit: 1644

1. Regarding applicants comments in the reply filed 6/18/2004, the previous Office action should have stated that claims 42,44-50,54-64,80-167 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in paper filed 12/3/2003.

2. Applicant's election with traverse of the species peptide of claim 43 and fused to a linker in the reply filed on 6/18/2004 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because of the following reasons. Regarding the different size peptides, it would create an undue burden on the Examiner to search additional species. Regarding applicant comments about species (d) versus species (b), the species of (d) does not contain a liposome and the species of (b) does not contain a linker.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 51,52,65,67-71,74,76,79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/18/2004.

4. Claims 41,43,53,66,72,73,75,77,78 are under consideration.

5. The oath or declaration is defective. The oath is defective because it contains priority claims to various US applications to which priority is no longer claimed. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

6. Applicant is required to update the status of all US patent applications disclosed in the specification.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 41,43,53,66,72,73,75,77,78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,602,510. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the two sets of claims differ in scope, the composition of claim 1 contains the elected peptide species recited in claim 41. The composition of claim 1 is a mixture of peptides. The use of amino acid linkers to join peptides to other molecules is well known in the art (also see claim 5). The composition of claim 2 would also contain a fluid phase which would constitute a pharmaceutically acceptable carrier (such as tissue culture media, etc).

9. Claims 41,43,53,66,72,73,75,77,78 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31,35-39 of copending Application No. 10149915. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the two sets of claims differ in scope, the composition of claim 1/18/31 contains the elected peptide species recited in claim 41. The composition of claim 1/18/31 is a mixture of peptides. The composition of claim 6 recites an amino acid linker joined to the claimed peptide.

Art Unit: 1644

The composition of claim 31 has a pharmaceutically acceptable carrier.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 41,43,53,66,72,73,75,77,78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grey et al. (WO 94/20127) in view of Panicali et al. (US Patent 6,001,349).

Grey et al. teach 9mer peptides derived from cancer specific antigens which bind HLA 2.1 (see page 3, first and second paragraphs, page 6, first paragraph, page 21, last paragraph). Grey et al. teach said peptide attached to an amino acid linker (see page 9, second paragraph). Grey et al. teach a composition of said peptide and pharmaceutically acceptable carrier (see page 24, first incomplete paragraph). Grey et al. teach that the composition can have additional peptides (see page 26, first paragraph). Grey et al. teach a motif that can be used to screen a cancer antigen for peptides which bind HLA 2.1 (see page 6, first paragraph and Table 9, page 50). Grey et al. teach that said motif can be used to identify T cell epitopes from cancer related antigens (see page 6, first paragraph). Grey et al. do not teach the particular CEA


derived peptide recited in the claims. Panicali et al. teach the human cancer antigen CEA and that its amino acid sequence was known in the art (see column 1, last paragraph, continued on column 2). The claimed peptide is part of CEA. A routineer would have used the motif disclosed by Grey et al. to produce a library of CEA derived peptides for characterization of whether said peptides are immunogenic. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Grey et al. teach a motif that can be used to identify 9mer peptides derived from cancer specific antigens which bind HLA 2.1 and that said motif can be used to identify T cell epitopes from cancer related antigens whilst Panicali et al. teach the human cancer antigen CEA and that its amino acid sequence was known in the art (see column 1, last paragraph, continued on column 2). The claimed peptide is part of CEA. One of ordinary skill in the art would have been motivated to do the aforementioned because Grey et al. teach a motif that can be used to screen a cancer antigen for peptides which bind HLA 2.1 (see page 6, first paragraph and Table 9, page 50) and that said motif can be used to identify T cell epitopes from cancer related antigens (see page 6, first paragraph). In addition, Panicali et al. disclose that it is desirable to identify CEA derived T cell epitopes (see column 1, penultimate paragraph).

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chari can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1644

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RON D. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 (60)

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644